

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-1195V

Filed: April 8, 2016

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SHANNON AND WILLIAM POWERS,
Parents and Natural Guardians of L.P., a minor,

Petitioners,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

* * * * *

PUBLISHED

Special Master Hamilton-Fieldman

Dismissal Decision; Statute of
Limitations; Equitable Tolling; First
Symptom or Manifestation of Onset;
Human Papillomavirus (“HPV”)
Vaccine; Gardasil; Stomach Pain;
Nausea; Bloating; Insomnia;
Sweating; Chills.

James B. Blumenstiel, Blumenstiel Falvo, LLC, Dublin, OH, for Petitioners.

Amy P. Kokot, United States Department of Justice, Washington, DC, for Respondent.

DECISION GRANTING RESPONDENT’S MOTION TO DISMISS¹

On December 12, 2014, Shannon and William Powers (“Petitioners”) filed a petition for compensation under the National Vaccine Injury Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act” or “Program”), on behalf of their minor child, L.P. Petitioners allege that L.P. developed “stomach pain, bloating, feeling full, nauseated and bladder infection-like symptoms” after receiving her first Human Papillomavirus (“HPV”) ³ vaccination on March 30, 2011.

¹ Because this published decision contains a reasoned explanation for the action in the case, the undersigned intends to post this decision on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002, codified as amended at 44 U.S.C. § 3501 note (2012). As provided by Vaccine Rule 18(b), each party has 14 days within which to file a motion for redaction “of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). In the absence of such motion, the entire decision will be available to the public. *Id.*

² National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

³ The petition refers interchangeably to L.P.’s “HPV vaccination” and “Gardasil.”

Petition at 1. They allege that L.P.'s second and third HPV vaccinations, administered on August 8, 2011 and December 12, 2011, exacerbated her symptoms and caused new symptoms including "insomnia, night sweats, day sweats, and chills." *Id.*

Having reviewed the petition and supporting documents, including numerous medical records, Respondent filed a Motion to Dismiss on July 21, 2015. *See* Respondent's Motion to Dismiss ("Motion"). In her Motion, Respondent asserts that Petitioners' case must be dismissed because it was filed "after the expiration of the statutorily prescribed limitations period, set forth in Section 16(a)(2) of the Vaccine Act." *Id.* at 2. In their Response, which was filed on August 6, 2015, Petitioners asserted that equitable tolling should apply to preserve Petitioners' claim. *See generally* Petitioners' Memorandum Contra ("Response").

Based on the record as a whole, and for the reasons set forth below, the undersigned hereby **GRANTS** Respondent's Motion.

I. Facts

L.P. received a series of three HPV vaccinations on March 30, 2011, August 8, 2011, and December 12, 2011. Petitioners' Exhibit ("Pets. Ex.") 22 at 5. Prior to vaccination, L.P. was deemed to be "[w]ell developed, well nourished, [and] well groomed" and was noted to be "[a]lert and active." Pets. Ex. 22 at 6. Although she saw her primary care physician ("PCP"), Dr. Linda Iskra, intermittently for complaints such as dermatitis, headaches, pharyngitis, and urinary tract infections and was hospitalized in 2009 for "episodic abdominal pain", L.P. was healthy and developing normally. Pets. Ex. 22 at 3-4, 6; Pets. Ex. 23B at 4.

On February 19, 2011, about six weeks before L.P. received her first HPV vaccination, she was admitted to Nationwide Children's Hospital. Pets. Ex. 22 at 42. L.P.'s chief complaint was abdominal pain, but she reported nausea, vomiting, abdominal tenderness with palpation, and burning after urination. Pets. Ex. 23C at 2. The initial impression was right lower quadrant pain and nausea; during her hospitalization, she had an appendectomy⁴ and an exploratory laparoscopy for bilateral ovarian torsion⁵. Pets. Ex. 22 at 42; Pets. Ex. 23C at 3, 10. It was noted that "[p]rior to the surgery [L.P.] had intermittent lower abdominal pains for 6 months which accelerated on 2/19/11." Pets. Ex. 22 at 45. The final diagnosis was a dead left ovary and right ovarian torsion. Pets. Ex. 23C at 12. She was discharged on February 21, 2011, with medication including Miralax (a laxative) and Hydrocodone (pain medication), and she was told to avoid rough activity and participation in sports until March 7, 2011. Pets. Ex. 22 at 42-43.

⁴ The physicians removed L.P.'s appendix even though it "appeared normal." Pets. Ex. 23C at 11.

⁵ The procedures she underwent included a "[l]eft oophorectomy, de-torsion and pexy of right ovary to uterus, lysis of adhesions, incidental appendectomy, [and] incidental umbilical hernia repair." Pets. Ex. 22 at 45; Pets. Ex. 23C at 12.

L.P. followed up at a pediatric surgery clinic on March 9, 2011. Pets. Ex. 23E at 12. It was noted that “[L.P.] is doing well, her previous symptoms resolved”; however, she still had “occasional pain after urination . . . [and her] [m]om [was] concerned about stomach bloating.” Pets. Ex. 23E at 15. L.P. received her first HPV vaccination shortly after this visit, on March 30, 2011. Pets. Ex. 27A at 7. L.P. received her second vaccination on August 8, 2011. *Id.* About two months after this visit, on September 30, 2011, L.P. presented to Dr. Don Bremer, an ophthalmologist, for an eye exam. Pets. Ex. 25 at 6-7. Her exam was normal and she was told to follow up in a year. *Id.*

The next recorded medical visit was on December 12, 2011. Pets. Ex. 27A at 19-22. It was noted that L.P. was “having right side pain 2 weeks prior to her periods,” needed the third HPV vaccination, and had “[d]aily bloating after eating”. Pets. Ex. 27A at 21-22. She returned to the doctor on December 16, 2011 and on January 9, 2012. Pets. Ex. 27B at 1-10. During the January 9th visit, Ms. Powers reported that L.P. had abdominal pain, bloating, and fatigue. Pets. Ex. 27B at 6-7. Dr. Geri Hewitt recommended that L.P. continue with Miralax to encourage regular bowel function, and ordered a pelvic ultrasound and bloodwork. Pets. Ex. 27B at 7. L.P.’s bloodwork and ultrasound results were within normal limits. Pets. Ex. 27B at 6, 13.

L.P. did not see another medical provider until August 31, 2012, when she was seen by Dr. Kimberly Shepherd, an OB/GYN. Pets. Ex. 26 at 13. Her chief complaint at this visit was bloating and it was noted that she was not in distress and appeared well nourished and developed; however, “about 6-8 months after surgery she started complaining of nausea and bloating as well as occasional discomfort.” Pets. Ex. 26 at 13-14. Her birth control pills were changed and a pelvic exam was ordered. Pets. Ex. 26 at 14. On December 10, 2012, she returned to Dr. Shepherd for a follow-up visit. Pets. Ex. 26 at 10-12. During this visit, L.P. did not report any symptoms and stated that she did not have abdominal pain. Pets. Ex. 26 at 10-11. L.P. presented to Dr. Shepherd a year later, on December 27, 2013, for her annual visit with complaints of cramping, but no other symptoms were noted during this visit. Pets. Ex. 26 at 9.

Again, there was a lapse in medical treatment and L.P.’s next noted medical visit was on February 10, 2014. On this date, L.P. presented the emergency room with dysuria⁶ and was discharged on the same day. Pets. Ex. 27B at 15. Two days later, L.P. presented the emergency room again for dysuria and again was discharged the same day. Pets. Ex. 27B at 21. During the second visit, it was noted that L.P. had pain and burning with urination, but did not have abdominal pain; the emergency physician’s impression was dysuria. Pets. Ex. 27C1 at 1-4.

L.P. sought treatment at the Emergency Room on June 11, 2014 for “consistent headaches for two months, pain increasing.” Pets. Ex. 27D at 2-3. The clinical impression was chronic headache and she was treated with a migraine cocktail. Pets. Ex. 27D at 5-7.

L.P. continued to seek treatment for a variety of conditions including headaches, blurry vision, migraines, optic disc abnormalities, fatigue, generalized pain, pelvic pain, urinary pain, overactive bladder, irritable bowel syndrome, heart palpitations, and joint pain. Pets. Ex. 27D at

⁶ Dysuria is defined as painful, or difficult urination. *Dorland’s Illustrated Medical Dictionary* (“*Dorland’s*”), 585 (32d ed. 2012).

2-3; Pets. Ex. 27E at 20, 22; Pets. Ex. 27F at 3, 21, 25; Pets. Ex. 27G at 8, 12, 20; Pets. Ex. 27I at 21; Pets. Ex. 27J at 18; Pets. Ex. 26 at 3, 6, 7. L.P. began seeing Dr. Phillip C. DeMio in the fall of 2014. *See generally* Pets. Ex. 24. Dr. DeMio's records are illegible, but lab results were included with his medical records. *See generally* Pets. Ex. 24B, 24C. In L.P.'s other medical records, it was repeatedly noted that Dr. DeMio had diagnosed L.P. with an immune deficiency disorder, metabolic disorder, and encephalopathy, and also that L.P. had a history of irritable bowel syndrome ("IBS"), and Lyme disease. Pets. Ex. 23E at 12.

II. Procedural History

Petitioners filed the case on December 12, 2014, along with several medical records and other documents, including an affidavit and notes from Shannon Powers and medical literature about the HPV vaccination. Pet.; Petitioners' Exhibits ("Pets. Exs.") at 1-20⁷. After Petitioners filed multiple motions for extension of time to file additional medical records, they filed 8 medical records and a statement of completion on March 12, 2015. Pets. Exs. 21-29; Statement of Completion. Petitioners continued to file medical records and filed a second statement of completion on May 28, 2015. Pets. Exs. 30, 31, 32; Statement of Completion.

Respondent filed her Rule 4(c) Report on June 10, 2015, in which she recommended against compensation. *See generally* Respondent's Report. In support of her contention, Respondent stated that "Petitioners have not demonstrated by preponderant evidence that L.P. suffered a medically-recognized injury . . . [n]o medical theory connects the HPV vaccine to L.P.'s alleged injury . . . [and] L.P.'s mother's affidavit renders the petition untimely-filed." Respondent's Report, at 11-12. Following the filing of Respondent's Report, Petitioners filed two additional medical records. Pets. Exs. 33, 34.

On July 21, 2015, Respondent filed a Motion to Dismiss. *See generally* Motion. In her Motion, Respondent argues that the case should be dismissed because the injury from which L.P. suffers is unclear and the petition was filed after the statute of limitations period expired. Motion, at 4-7.

Following the filing of Respondent's Motion, Petitioner filed another set of medical records, and a supplemental⁸ letter from one of L.P.'s treating physicians, Dr. DeMio. Pets. Ex. 35-36. In this letter, Dr. DeMio asserted that "it is my diagnosis that the HPV vaccination series [L.P.] received is the major cause of her problems." Pets. Ex. 35 at 1. He suggested a medical theory by indicating that "[p]eople who have become sick in a sequence like [L.P.]'s have been shown to exhibit physiology that results from the combination of aluminum & the viral DNA." *Id.* He concluded by stating that L.P.'s symptoms have not shown significant improvement and that her "problems are permanent". *Id.*

⁷ These exhibits were originally filed on a compact disc; however, the disc was damaged. Therefore, the exhibits were refiled on April 14, 2015. Notice of Filing.

⁸ Petitioners originally filed a letter from Dr. DeMio with their Petition. Pet. Ex. 7. The initial letter noted only that L.P. was a patient and that she was undergoing testing to determine an appropriate course of treatment. *Id.*

On August 6, 2015, Petitioners filed a Response to Respondent's Motion, along with several additional medical records. "Pets. Response"; Pets. Exs. 37-41. Petitioners conceded that the petition had been filed after the statute of limitations had run, but argued that equitable tolling should be applied in this case because L.P.'s doctors had failed to recognize that her injuries might be vaccine related, and that this failure should be considered an extraordinary circumstance that warrants equitable tolling. *Id.* at 7-11. Petitioners also explained that the opinion filed by one of L.P.'s treating physicians, Dr. DeMio, supported their contention that the vaccinations caused L.P.'s condition. *Id.* at 11-12.

Respondent filed a Reply to Petitioners' Response to Respondent's Motion on August 25, 2015. Respondent's Reply to Petitioners' Response to Respondent's Motion to Dismiss ("Reply"). Respondent argues that equitable tolling should not be applied in this case and that Petitioners' petition remains untimely filed. *Id.* at 2-5. Respondent argues that no extraordinary circumstances exist in this case, that the nature of the alleged injury remains unclear, and that there is no theory of causation linking the vaccinations to the injury alleged in this case. *See generally id.* Following the filing of the Reply, Petitioners filed one additional medical literature article. Pets. Ex. 42. This matter is now ripe for adjudication.

III. Applicable Legal Standard

The Vaccine Act requires that if a vaccine is administered after October 1, 1988, a Petition for compensation must be filed within "36 months after the date of the occurrence of the first symptom or manifestation of onset [of the alleged vaccine injury]." 42 U.S.C. § 300aa-16(a)(2). This timing requirement, known as the statute of limitations, is strictly adhered to and is triggered by the first symptom or manifestation of onset, whichever occurs first. *Markovich v. Sec'y of Health & Human Servs.*, 477 F.3d 1353, 1357 (Fed. Cir. 2007). "A symptom may be indicative of a variety of ailments"; alternatively, "[a] manifestation of onset is more self-evident of an injury and may include significant symptoms that clearly evidence an injury." *Markovich v. Sec'y of Health & Human Servs.*, 477 F.3d 1353, 1357 (Fed. Cir. 2007).

Equitable tolling is recognized under the Vaccine Act; it can be invoked to toll the statute of limitations when an extraordinary circumstance exists, such as fraud or duress. *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322, 1344-45 (Fed. Cir. Aug. 5, 2011). However, the fact that a petitioner is "unaware[]" of a causal link between an injury and administration of a vaccine" before the statute of limitations deadline has passed is not such an extraordinary circumstance. *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322, 1345 (Fed. Cir. Aug. 5, 2011).

IV. Analysis

A. Petitioners' claim fails to meet the requirements of 42 U.S.C. §300aa-16(a)(2)

In her Motion to Dismiss, Respondent argues that Petitioners' claim fails to meet the requirements of 42 U.S.C. §300aa-16(a)(2) because Petitioners filed their claim after the expiration of the relevant statute of limitations period. Motion at 2. Based on Petitioners'

concession and on the record as a whole, the undersigned finds that Petitioners did not file their claim before the expiration of the statute of limitations.

The Petition was filed on December 12, 2014; therefore, the first symptom or manifestation of onset must have occurred no earlier than December 12, 2011, for the claim to be timely. L.P. received the HPV vaccinations on March 30, 2011, August 8, 2011, and December 12, 2011. Pets. Ex. 22 at 5. Although it is unclear from the medical records and supporting documentation which condition Petitioners' are alleging was caused by these vaccinations, Ms. Powers stated that L.P.'s symptoms of "stomach pain, bloating, feeling of being full, nauseated, and what seemed like a bladder infection" began "almost immediately" after the first vaccination. Pets. Ex. 1 at 2; Pets. Ex. 34 at 1. She also indicated that L.P.'s condition worsened after each vaccination. Pets. Ex. 1 at 2. L.P.'s affidavit is consistent with these assertions. Pets. Ex. 39 at 2.

There are no medical records between the dates of L.P.'s first and third vaccinations that mention any of the symptoms reported in Ms. Powers' or L.P.'s affidavits, nor are the repeated calls to doctors Ms. Powers purportedly made during this time noted in those records. *See* Pets. Ex. 27A at 10; Pets. Ex. 25 at 6-7; Pets. Ex. 1; Pets. Ex. 39 at 3. However, the records from L.P.'s visit to her gynecologist, Dr. Kimberly Shepherd, on August 31, 2012, reflect that "[a]bout 6-8 months after [February 20, 2011] surgery [to correct bilateral ovarian torsion] she [L.P.] started complaining of nausea and bloating as well as occasional discomfort," Pets. Ex. 26 at 13, which would place onset at approximately August-October 2011.

The undersigned finds that, whether the onset date is March 30, 2011, based on the affidavits, or August-October 2011, based on the medical records, the onset of L.P.'s allegedly vaccine-caused injury predates the cutoff date of December 12, 2011 by several months. Therefore, Petitioners' claim was untimely filed.

B. Petitioners' claim fails to meet the requirements of equitable tolling

Petitioners' pleadings repeatedly refer to L.P.'s young age, *see, e.g.*, Pets. Response at 1, 2, 3, and assert that "L.P. had no mental or legal capacity to determine her doctors were wrong when providing her mother and her misinformation." *Id.* at 3. There is no legal age of majority provision in the Vaccine Act, however, nor is there a single case decided under the Act that imputes such a provision into the Act. The application of the statute of limitations to Petitioners' claim is not tolled on that basis.

Petitioners acknowledge, citing *Cloer v. Secretary of Health & Human Services*, that the Federal Circuit "declined to equate equitable tolling with a discovery rule." Pets. Response at 4. Nevertheless, they proceed to argue that the failure of L.P.'s doctors to diagnose her condition as a vaccine injury, and/or Petitioners' failure to discover an alleged link between the vaccine and L.P.'s condition, constitutes an "extraordinary circumstance" that warrants the application of equitable tolling. *Id.* at 5-13. This simply ignores the holding of *Cloer*, that the date of the first symptom or manifestation of onset "does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition." *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322, 1339 (Fed. Cir. Aug. 5, 2011). Why Petitioners did not know of a

potential link between L.P.'s injury and the vaccines, for example, because of misdiagnosis, is irrelevant; the triggering event for the statute of limitations, first symptom or manifestation of onset, is completely independent of a petitioner's understanding of the implications of that event under the Vaccine Act. *Id.* The undersigned understands that this provision seems grossly unfair to Petitioners. The undersigned must apply the law as written, however, and that law is not ambiguous. "Congress made the deliberate choice to trigger the Vaccine Act statute of limitations from the date of occurrence of the first symptom or manifestation of the injury for which relief is sought, an event that does not depend on the knowledge of a petitioner as to the cause of an injury. *Id.* at 1338. Petitioners' attempt to invoke equitable tolling in this case is denied.

V. Conclusion

Based on the record as a whole, the undersigned finds that Petitioners' claim was filed more than three years after "the date of the occurrence of the first symptom or manifestation of onset," as required by 42 U.S.C. § 300-16(a)(2), and that equitable tolling should not be applied. Therefore, **Respondent's Motion to Dismiss is GRANTED. In the absence of a motion for review, the Clerk shall enter judgment accordingly.**

IT IS SO ORDERED.

/s/ Lisa D. Hamilton-Fieldman
Lisa D. Hamilton-Fieldman
Special Master